DigbyGlobal

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Submitted via Website and
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Standing Committee on International Trade
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6
Canada

Subject: Canada's position with respect to a proposal at the World Trade Organization (WTO) to provide "a waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19" (Committee Meeting #23; April 16, 2021)

Dear Members of the Standing Committee on International Trade,

I encourage Canada to oppose the proposal at the WTO for a waiver of intellectual property obligations under TRIPS relating to COVID-19 vaccines[1] (the "TRIPS waiver").

Like Committee members, I agree the urgency could not be higher to distribute COVID-19 vaccines to all countries and peoples of the world. Global mass vaccination is justified on moral, human rights and economic grounds. On this we have an unparalleled degree of global consensus.

Committee members are rightly focused on the international trade mechanisms to accelerate, equitably, global distribution of COVID-19 vaccines.

But in my view, based on over 25 years direct involvement in international life sciences research and technology transfer, as a scientist and a lawyer,

- A TRIPS waiver will fail to accelerate equitable distribution of vaccines, will set false expectations about the objective, and will lead to dangerous vaccine safety risks.
- Instead, the Committee should call for the immediate acceleration of voluntary technology transfer by COVID-19 vaccine producers to the Global South.

My view is based on the fundamental technical problem that, in the case of COVID-19 vaccines, these products are new, innovative, and highly complex biologic agents. These are not simple small molecules like HIV drugs which have been the subject of previous TRIPS waiver disputes[2].

[1] WTO Meeting Report February 23, 2021 (https://bit.ly/2S6x3Hk)
[2] UN Development Programme Report, 2006. (https://bit.ly/3u6i66o)

Committee members understand the unprecedented achievement of having COVID-19 vaccines approved in under 12 months, and the important role of a small group of Canadians in laying the technical basis for many of them in patents and know-how[3].

Less well understood is the enormous complexity of the supply chain, manufacturing processes and quality control processes which are essential for the safety and scale of these vaccines[4]. Together these processes may be called "know-how". Know-how is typically not patented. Because it is so new, know-how developed for COVID-19 vaccines continues to evolve and improve. It is essential for large scale production of safe vaccines.

A TRIPS waiver would give businesses in the Global South the power to ignore patents[5,6] but it would not force the delivery of know-how to ensure safe and large-scale vaccine supply. A TRIPS waiver risks safety and sets false expectations for expanded vaccine supply. These risks, if realized, would set-back and delay global access to COVID-19 vaccines[7].

A TRIPS waiver attempts to circumvent the very real requirement for capacity building, technology transfer, and technical co-operation which is essential for a safe and large-scale vaccine supply. In fact, there are very few experts globally, all of whom are engaged in current vaccine production, and few of whom could be available to independently enable technology transfer.

Claims by generic businesses, and their supporters, that "they are ready" and "to ignore the paternalistic views of patent holders" must be viewed with serious skepticism. Many generic businesses are self-interested and stand to benefit from government grants and private financing if they can announce they are vaccine makers. Politicians succeed by enabling local businesses. But the reality of safe production at large scale may be far beyond their grasp[8]. In short, the mundane requirements of technology transfer cannot be circumvented by a TRIPS waiver.

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[3] For the vaccines of Pfizer/BioNTech and Moderna, see: Acuitas (https://bit.ly/2QG1lQQ) and Arbutus Biopharma (https://bit.ly/3eFQcYk); For the vaccines of AstraZeneca, Johnson & Johnson and CanSino, see: Dr. Frank Graham (https://bit.ly/3nKiyFb) (ret. McMaster University) and the National Research Council of Canada.

[4] By way of example the Pfizer/BioNTech vaccine supply chain involves 280 components, 86 suppliers and 19 countries. The manufacturing processes are novel and unlike any large-scale pre-existing products. Quality control is designed into the process with specific recipes and techniques. .

[5] More specifically, a TRIPS waiver would inoculate WTO member countries from WTO penalties for having granted export licenses for local businesses who ignore patents when they manufacture and ship products to buyers in other countries.

[6] The Committee witness Nathaniel Lipkus from IPIC explained that Canadian companies would be prohibited from supplying other countries under CETA, TPP and CUSMA Agreements.

[7] A tragic example of improper vaccine production by an untrained producer is found in the 1955 Cutter incident https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1383764/

[8] One Committee member cannot believe that India would call for a TRIPS waiver without being aware of the complexity of technology transfer. This view was answered by Committee witness Rachel Silverman who noted that calling for a TRIPS waiver improves India's negotiating position for voluntary technology transfer, but actual success with a TRIPS waiver would fail to deliver the valuable know-how and leave India with an empty victory.

Instead, I believe the Committee should use its powerful credibility to call for the immediate acceleration of voluntary technology transfer by the COVID-19 vaccine producers. Those businesses in the Global South most capable of manufacturing complex biologics should be first in line. Ambitious timelines and production goals should be established in collaboration with current producers.

Voluntary technology transfer will realistically meet the urgent need to expand COVID-19 vaccine production.

But a TRIPS waiver promises only a short-cut to a dead end.

Some Committee members still take the view "why not give it a try". Grant a TRIPS waiver and let the Global South make its own decisions about the safe supply of vaccines.

But there is no free ride. This view has a terrible cost.

- Betrayal and sacrifice of patent rights puts at risk both past and future investments in vaccine research.
- All life sciences research is inherently risky and patent rights are fundamental to ensuring a steady flow of research investment.
- Canadian inventors would suffer particular harm as it is their patents which underlie the global success of today's COVID-19 vaccines.
- Supporting a waiver would diminish Canada's reputation for intellectual property protection, and a emphasize we are a poor place for research investment.

It would be foolish to adopt a policy that is bound to fail, at such a high cost, when alternative multilateral global strategies have a much higher chance of success to ensure rapid large-scale deployment of safe vaccines in countries of the Global South. These include:

- Optimization of supply chain and health care delivery
- Sharing of vaccine supply from developed countries
- Cost reduction via multilateral contributions

In summary, I urge the Committee to call for the immediate acceleration of voluntary technology transfer by the COVID-19 vaccine producers to the Global South and to oppose the proposal at the WTO for a waiver of TRIPS obligations in regard to COVID-19 vaccines.

Yours truly,

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Thomas Digby, MSc., JD, is a Canadian and US attorney who has practiced for 25+ years with early-stage life science start-up companies on global intellectual property, technology transfer and regulatory strategy. He spent 10+ years with Novartis in Boston and Switzerland. He is now in practice in Vancouver.